

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Clark et al

Atty Docket No.: 0037.00

Application No. 09/414,388

Examiner: A. Lewis

Filed: 10-7-99

Group Art Unit: 3761

September 20, 2001

Title: FLOW RESISTANCE MODULATED
AEROSOLIZED ACTIVE AGENT
DELIVERY



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on September 20, 2001.

Signed: Kathy Honnert
Kathy Honnert

INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §1.56, §1.97 and §1.98

Commissioner for Patents
Washington, DC 20231

Dear Sir:

The references listed in the attached PTO Form 1449 may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

Copies of the references are enclosed, as required under 37 CFR §1.98. The references on the attached Form 1449 identified by an asterisk (*) were previously cited by or submitted to the PTO in a prior application relied upon for an earlier filing date. Accordingly, in compliance with 37 CFR §1.98 (d), copies of these references have not been provided.

Attorney Docket No. 0037.00

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:

☐ within three months of the filing date of a national application; within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or before the mailing date of a first Office action on the merits (whichever event occurs last);

☒ more than three months from the filing date of an application and after the mailing date of a first Office action on the merits, but before the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311 (whichever occurs first), and is accompanied by:

☒ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under §1.97(c) (\$180.00); or

☐ one of the following statements as specified in 37 CFR 1.97(e) that:

☐ each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in section 1.56(c) more than three months prior to the filing of the information disclosure statement; or

☐ after the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311, but on or before the payment of the issue fee, and is accompanied by each of:

☐ the following petition:
Applicant hereby requests consideration of the accompanying information disclosure statement;

☐ the petition fee set forth in 37 CFR 1.17(i) (\$130.00); and

☐ one of the following statements as specified in 37 CFR 1.97(e) that:

☐ each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three

months prior to the filing of the information disclosure statement; or

- ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in section 1.56(c) more than three months prior to the filing of the information disclosure statement.


- ☐ Attached is Check No. _ in the amount of \$0.
- ☒ Please charge the amount of \$180.00 to Deposit Account 500348.
- ☒ If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 500348.

Respectfully submitted,

INHALE THERAPEUTIC SYSTEMS, INC.

Dated: September 20, 2001

By:



Guy V. Tucker
Reg. No. 45,302

San Carlos, CA 94070
(650) 631-3100

Form 1449 (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0037.00	Application No.: 09/414,384
	Applicant: Clark et al.	
	Filing Date: 10-7-99	Group: 3761

U.S. Patent Documents

Examiner Initial	Patent No.	Date	Patentee	Class	Sub- Class	Filing Date
	2,587,215	2-26-1952	Priestly			
	3,837,341	9-24-1974	Bell			
	4,274,404	6-23-1981	Molzan et al.			
	4,442,856	4-17-1984	Betz			
	4,533,137	8-6-1985	Sonne			
	5,040,527	8-20-1991	Larson et al.			
	5,042,467	8-27-1991	Foley			
	5,301,666	4-12-1994	Lerk et al.			
	5,408,994	4-25-1995	Wass et al.			
	5,522,380	6-4-1996	Dwork			
	5,586,550	12-24-1996	Ivri et al.			
	5,823,183	10-20-1998	Casper et al.			
	5,855,202	1-5-1999	Andrade			
	5,884,620	3-23-1999	Gonda et al.			
	5,941,240	8-24-1999	Gonda et al.			
	6,029,663	2-29-2000	Eisele et al.			
	6,076,523	6-20-2000	Jones et al.			
	6,095,134	8-1-2000	Sievers et al.			
	6,116,238	9-12-2000	Jackson et al.			
	6,138,673	10-31-2000	Shepherd			
	6,142,146	11-7-2000	Abrams et al.			

Examiner:	Date Considered:
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449 (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0037.00	Application No.: 09/414,384
	Applicant: Clark et al.	
	Filing Date: 10-7-99	Group: 3761

Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication							
	A	WO97/40819	11-6-1997	PCT					
	B	WO00/21594	4-20-2000	PCT					
	C	WO99/46055	6-16-1999	PCT					
	D	WO98/32479	7-30-1998	PCT					
	E	1,598,053	9-16-1981	Great Britain					

Examiner:	Date Considered:
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Practitioner's Docket No. 0037.00



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Clark, Andrew et al.
Application No.: 09/414,384 Group No.: 1615
Filed: October 7, 1999 Examiner: Unassigned
For: FLOW RESISTANCE MODULATED AEROSOLIZED ACTIVE AGENT DELIVERY

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This Information Disclosure Statement

CERTIFICATION UNDER 37 C.F.R. sections 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)

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37 C.F.R. section 1.8(a)

☐ with sufficient postage as first class mail.

37 C.F.R. section 1.10*

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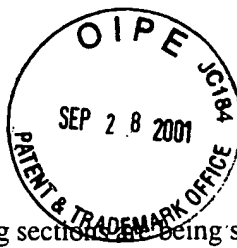
☐ transmitted by facsimile to the Patent and Trademark Office.

Date: 3/7/2000

Kathy Honnert
Signature

Kathy Honnert
(type or print name of person certifying)

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"Since the filing of correspondence under [section] 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.



The following sections are being submitted for this Information Disclosure Statement:

1. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)
2. Copies of Listed Information Items Accompanying This Statement
3. Identification of Person(s) Making This Information Disclosure Statement

Section 1. Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)

Section 2. Copies of Listed Information Items Accompanying This Statement

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

The person making this certification is:

- a. the practitioner who signs below on the basis of the information supplied by the inventor(s) and in the practitioner's file.

Date: March 2, 2000

Felissa H. Cagan
Signature of Practitioner

Reg. No.: 35,089
Tel. No.: 650-631-3100
Customer No.: 21968

Felissa H. Cagan
Inhale Therapeutic Systems, Inc.
150 Industrial Road
San Carlos, CA 94070

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96)

Appr
Patent and Trademark

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Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	09/414,384
Filing Date	10/07/1999
First Named Inventor	Andrew Clark
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	0037.00

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner
Signature**

Date	
Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	09/414,384
		Filing Date	10/07/1999
		First Named Inventor	Andrew Clark
		Group Art Unit	1615
		Examiner Name	Unassigned
		Attorney Docket Number	0037.00
(Use as many sheets as necessary)			
Sheet	1	of	1

SEP 28 2001

[illegible]

Examiner Signature		Date Considered	
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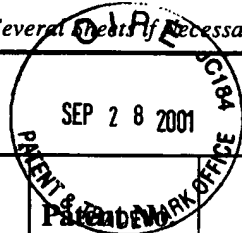
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¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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Form 1449 (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets If Necessary)</i>	Atty Docket No.: 0037.00	Application No.: 09/414,384
	Applicant: Clark et al.	
	Filing Date: 10-7-99	Group: 3761

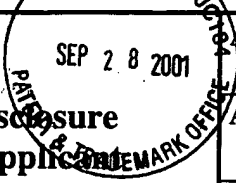


U.S. Patent Documents

Examiner Initial	Patent No.	Date	Patentee	Class	Sub- Class	Filing Date
	3,788,310	1-29-1974	Fleischmann			
	4,106,503	8-15-1978	Rosenthal et al.			
	4,484,577	11-27-1984	Sackner et al.			
	4,627,432	12-9-1986	Newell et al.			
	4,677,975	7-7-1987	Edgar et al.			
	4,778,054	10-18-1988	Newell et al.			
	4,811,731	3-14-1989	Newell et al.			
	5,284,133	2-8-1994	Burns et al.			
	5,419,315	5-30-1995	Rubsamen			
	5,558,085	9-24-1996	Rubsamen et al.			
	5,622,166	4-22-1997	Eisele et al.			
	5,692,492	12-2-1997	Bruna et al.			
	5,873,358	2-23-1999	Gonda et al.			
	5,993,421	11-30-1999	Kriesel			
	6,085,753	7-11-2000	Gonda et al.			

Examiner:	Date Considered:
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Form 1449 (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0037.00	Application No.: 09/414,384
Applicant: Clark et al.		
Filing Date: 10-7-99		Group: 3761

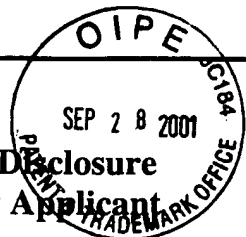
Foreign Patent or Published Foreign Patent Application

Examiner Initial		No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No	
		A	WO99/27987	6-10-1999	PCT				
		B	WO95/34337	12-21-1995	PCT				
		C	WO99/47196	9-23-1999	PCT				
		D	WO95/24183	9-14-95	PCT				

Examiner:	Date Considered:
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449 (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0037.00	Application No.: 09/414,384
	Applicant: Clark et al.	
	Filing Date: 10-7-99	Group: 3761



Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	E	Clark et al. "The Relationship Between Powder Inhaler Resistance and Peak Inspiratory Conditions in Healthy Volunteers- Implications for In Vitro Testing" Journal of Aerosol Medicine, vol. 6, no. 2, pp. 99-110, 1993.
	F	Hill, "Characteristics of an Active, Multiple Dose Dry Powder Inhaler" Respiratory Drug Delivery IV, pp 109-116 (1994).
	G	Dolovich "Physical Principles Underlying Aerosol Therapy" Journal of Aerosol Medicine, vol. 2, no. 2, pp. 171-186, 1989.
	H	Clark "Effect of Powder Inhaler Resistance Upon Inspiratory Profiles in Health and Disease" Respiratory Drug Delivery IV, pp. 117-123, (1994).
	I	Ross et al. "Effect of Inhalation Flow Rate on the Dosing Characteristics of Dry Powder Inhaler (DPI) and Metered Dose Inhaler (MDI) Products" Journal of Aerosol Medicine, vol. 9, no. 2, pp. 215-226 (1996).
	J	Lawford et al. "Pressurized Aerosol Inhaler Techniques: How Important are Inhalation from Residual Volume, Inspiratory Flow Rate and the Time Interval Between Puffs?" J. Dis. Chest, 77, pp. 276-281 (1983).

Examiner:	Date Considered:
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO Acknowledgment Postcard - File Copy

Application Type	Filed Application	Date Sent	08/31/2001
Practitioner Docket No.	0037.00	Customer No.	21968
Application No.	09/414,384		

Examiner	A. Lewis	Group Art Unit	3761
Mail Service	First Class Mail		

Inventor(s) Andrew Clark

Invention Title FLOW RESISTANCE MODULATED AEROSOLIZED ACTIVE AGENT DELIVERY

<u>Documents Submitted</u>	<u>Sent</u>	<u>pages</u>		<u>Sent</u>	<u>pages</u>
Oath or Declaration			Drawings		
Transmittal		1	form 1449		3
Fee Transmittal		1	References		
Amendment		7			
IDS		3			

Contact Person	Felissa H. Cagan	Contact No.	650 631 3145
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